Aims and Objectives

To test the hypothesis that consensus estimates using best available data on PrEP need, uptake and duration of use are correct and, if not, provide accurate measures across the complexity of the population likely to benefit from this medicinal product. This is required to determine the commissioning of future access to PrEP.

Inclusion:
The participant populations for this trial will be men and women attending GUM clinics who belong to one of three populations recognised to be at high risk for HIV, namely:

A. Men (cisgender and transgender) and transgender women who:
   1. Have sex with men
   2. Have had an HIV negative test during an earlier episode of care in the preceding year
   3. Report condomless intercourse (excluding oral) in the previous 3 months
   4. Affirm their likelihood of having condomless (excluding oral) intercourse in the next 3 months

B. HIV negative partners of an HIV positive person when:
   1. The HIV positive partner is not known to be virally suppressed (<200 copies/ml for 6 months or more)
   2. Condomless intercourse (excluding oral) is anticipated before treatment of the HIV positive partner takes effect

C. HIV negative persons who:
   1. Are clinically assessed and considered to be at similar high risk of HIV acquisition

Participants will therefore be considered eligible for trial enrolment if they fulfil all the following criteria:

1) Belong to one of the three at high HIV risk populations described above
2) Aged 16 years or over (no upper limit)
3) Considered to be HIV negative on the day of enrolment
4) Willing and able to provide informed consent
5) Willing to adhere to the recommended PrEP regimen
6) Willing to re-attend the trial clinic at appropriate intervals for risk assessment

Exclusion:
Participants will not be considered eligible for trial enrolment if they fulfil any of the following criteria:

1) An acute viral illness that could be due to HIV seroconversion
2) Any contraindication to Tenofovir Disoproxil (TD)/ Emtricitabine (FTC)